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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,100	09/10/2003	Paul Albert Sagel	9031	4328

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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06/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,100	Applicant(s) SAGEL ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10, 19-28, 30, 31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10, 19-28, 30, 31, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed March 31, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness

1) Claims 8-10, 19, 20, 22, 28, 30, 31 and 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Leaderman (2002/0061329).

Applicant's Arguments

Applicant argues that porous backings are used for non-oral care applications as disclosed by paragraph 21. Additionally, even if a porous backing could be used in the

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oral cavity, the Office Action has pointed to no teaching regarding the use of the dressing within the oral cavity which would allow the inference of the existence of void spaces which extend through the thickness of the film (claim 19) or void spaces that extend from the first side of the mesh to the second side of the mesh where the fiber coating partially fills the void spaces (claim 28). Just because material can pass through the pores of the backing layer does not mean that the same material can pass through the dressing or that, if it does, it passes in the same way. Further, the office Action points to no discussion of the degree to which the fibers are coated and whether the coating would likewise cover the holes in the dressing. Applicants can find no way of determining what is not coated based on the disclosure in Leaderman.

Applicants contend they can find no teaching in Leaderman relating to how any of the methods of coating listed in Leaderman would lead to a product which would have void spaces which would extend through the thickness of the film (claim 19) or would result in a partial filling of the mesh (claim 28). Additionally, if considered an inherent property, inherency may not be established by "probabilities or possibilities". "The mere fact that a certain thing may result from a given set of circumstances is not sufficient". As such, it is respectfully submitted that Leaderman does not establish a *prima facie* case of obviousness because the Office Action fails to point to teachings relating to all of the limitations of independent claims 19 and 28.

Examiner's Response

The Examiner submits the dressings of the reference are particularly useful for topical application to the oral cavity (paragraph 0015). The carrier may be a gauze (which has voids that would extend from the first side of the gauze to the second side, encompassing claim 28) and becomes impregnated with the gels and then dried (paragraph 0014). It is reasonable to conclude that when dried the gel will coat the fibers of the gauze leading to voids in the device. Further, as asserted by Applicant, paragraph 0017 and 0018 encompass oral care, and paragraph 0018 discloses the backing may also be porous. Thus, porous backings may be used for oral and non-oral applications. Additionally the compositions may be applied using a carrier/gel system which would include the gel and a material including a porous material which may also be a gauze material. Thus the dressing would not have a backing layer at all. Considering that the carrier/gel dressings are dried and then hydrated in order to deliver the oral care or active to the teeth, it is reasonable to conclude that this indicates that voids (which would encompass any size voids) are present in the compositions to allow saliva to penetrate the dressing to release the actives to the oral cavity.

Furthermore, for *arguendo*, even if this not the case, as previously stated, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than

the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

It has been disclosed by the reference to coat a material comprising “voids” to deliver oral active to the oral cavity. Applicant has not shown that the device of the instant claims show an improvement over that of the prior art by showing the improvement is more than predictable use of prior art elements according to their established functions. Such as, that by having holes or voids all the way through the product will lead to enhanced activity. Leaderman provides a substrate similar to that recited in the instant claims by disclosing gauze or porous substrates, which would encompass the mesh of the instant claims. The reference further teaches that the fibers of these substrates are covered with the films or gels, and actives to be delivered to the teeth include whitening agents. These factors strongly suggest that the devices of Leaderman have voids that extend through the thickness of the film.

2) Claims 10, 19, 20, 22 and 28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544).

Applicant's Arguments

Applicant argues that the office Action points to no discussion of the degree to which the fibers are coated and whether the coating would likewise cover the holes in the dressing. Additionally, there is no way of knowing whether unabsorbed material on the surface of a fiber is partially covering a hole or just sitting on top of a portion of the fiber. Applicants can find no way of determining what is not coated based on the disclosure in Jones. Additionally, assuming the Office Action characterization of Jones is correct with respect to the teachings of a perforated whitening layer and a porous backing layer, the Office Action has pointed to no teachings of the interplay of these two layers. Thus, there is no way of knowing whether the combination of these two layers would result in holes that pass all the way through the device as contended in the Office Action. Additionally, if considered an inherent property, inherency may not be established by "probabilities or possibilities". "The mere fact that a certain thing may result from a given set of circumstances is not sufficient". As such, it is respectfully submitted that Jones does not establish a prima facie case of obviousness because the Office Action fails to point to teachings relating to all of the limitations of independent claims 19 and 28.

Examiner's Arguments

The Examiner submits that Jones discloses that the whitening gel may be impregnated into the absorbent's material's bulk. The oral care layer may also be in the

form of a perforated layer, encompassing voids. When a perforated film is on a porous backing layer, which may be porous and have voids, this suggests the voids extend through the device. The gel can soak into the absorbent fabric, which may be woven or nonwoven, and can be completely absorbed by the material, or some may remain unabsorbed as a surface layer (paragraphs 0047 and 0048). Based on this disclosure, it is reasonable to conclude that some of the gel partially fills the voids, especially when the gel is completely absorbed by the material, thereby, encompassing the limitation partially filling the mesh and voids that extend through the film as recited in the instant claims. The gel may also be placed in patches on the backing (see Drawings). When the backing is a fabric in this case, it is reasonable to conclude that the voids in the uncovered areas of the backing will meet the limitation of the voids spaces extending through the thickness of the film.

Furthermore, for *arguendo*, even if the was not the case, as previously stated, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter

of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742. Applicant has not shown that the device of the instant claims show an improvement over that of the prior art by showing the improvement is more than the predictable use of prior art elements according to their established functions. Jones provides a substrate similar to that recited in the instant claims by disclosing woven or non-woven fabric and a material perforated with holes (paragraph 0016). It is also disclosed that these substrates are coated with an active composition, the composition is absorbed into the material or the composition is applied in patches. These factors strongly suggest that the devices of Jones have voids (which would encompass any size voids) that extend through the thickness of the film.

3) Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544) in view of Ruben (US 6,146,655).

Applicant's Arguments

It is respectfully submitted that Jones in view of Ruben does not establish a prima facie case of obviousness because the combination does not teach or suggest all of the claim limitations of independent claim 19, from which claim 7 depends. The deficiencies of Jones with respect to independent claim 19 are discussed above and the Office Action points to no teaching in Ruben which would cure its deficiencies.

Examiner's Response

In regards to Jones et al., see Examiner's Response above. Ruben discloses the parameters of fiber used in drug delivery systems and therefore fills the deficiencies of Jones et al.

4) Claims 21, 23-27 and 33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544) in view Chen et al. (US 6,261,679).

Applicant's Arguments

As stated above, Applicants contend the Office fails to point to direct teachings in Jones regarding a product which would have void spaces which would extend through the thickness of the film (claim 19) or would result in a partial filling of the mesh (claim 28). The discussion with regard to claim 28 is similarly applicable to claim 23. Additionally, if considered an inherent property, inherency may not be established by "probabilities or possibilities". "The mere fact that a certain thing may result from a given set of circumstances is not sufficient". It is respectfully submitted that Jones in view of Chen does not establish a prima facie case of obviousness.

Examiner's Response

In regards to Jones et al., see Examiner's Response above. Chen discloses the benefits of using hydratable polymers as fibers in dental absorbents and therefore fills

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the deficiencies of Jones et al. In regards to 23-27, Jones et al. disclose all the limitations required by the claims except for the fibers of the mesh being hydratable polymers. See Examiner's Response above. Chen cures this deficiency by disclosing why one of ordinary skill in the art would want to use water hydratable polymers as the fibers of Jones et al., which is to increase the integrity and resiliency of the device without subtracting from absorbent attributes desired in an absorbent material, as disclosed by Chen et al., therefore encompassing claims 23-27 and 33.

Claims 7-10, 19-28, 30, 31, 33 and 34 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612